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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/725,698

12/01/2003

Stephen D. Pacetti

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7590

09/03/2009

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EXAMINER

NGUYEN, PHU HOANG

ART UNIT

PAPER NUMBER

1791

MAIL DATE

DELIVERY MODE

09/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/725,698	Applicant(s) PACETTI, STEPHEN D.	
	Examiner PHU H. NGUYEN	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 76-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/28/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 79-80 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 79 and 80 recites "the temperature is between -60 deg. C and room temperature" and "the temperature is between room temperature and the glass transition temperature" respectively; these limitations does not further limit the independent claim 76 wherein the temperature is below room temperature.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 76-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hijlkema et al. (U.S Pub. No. 20020143382) in view of Pacetti (U.S Patent No. 6574497) and further in view of Rosenthal et al. (U.S Pub. No. 2003/0144727).

Regarding claims 76, 81-82 and 83, Hijlkema (Abstract and paragraphs 6 and 28) discloses a method of making a medical device comprising:

- providing a stent having a coating comprises a polymer,
- positioning the stent on a balloon of a catheter assembly; and

Art Unit: 1791

mounting the stent on the balloon with thermal regulation to increase hardness by crimping.

Hijkema discloses the coating comprises a polymer (paragraph 21) and a polymer can have a T_g below or above ambient temperature depending on the ambient temperature and the temperature of the existing surface of the coating may be either heated or cooled (paragraph 30) but does not expressly disclose the polymer as poly(vinylidene fluoride-co-hexafluoropropylene), it is well known to use a fluorine containing elastomer such as copolymers of chlorotrifluoroethylene and vinylidene fluoride to be affixed to a medical device, for purposes such as imaging as evidenced by Pacetti (column 9, lines 5-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use poly(vinylidene fluoride-co-hexafluoropropylene) to affix to a medical device as taught by Pacetti.

Although the combination of Hijkema and Pacetti does not disclose the property of the poly(vinylidene fluoride-co-hexafluoropropylene), it is submitted that poly(vinylidene fluoride-co-hexafluoropropylene) inherently has the claimed properties of glass transition temperature being below room temperature and shore hardness being 60A to 80D or 80A to 60D.

Furthermore, Hijkema discloses increasing the shore hardness of the polymer but does not expressly disclose the percentage of increase. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (see *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). Therefore, it would have been obvious to one

Art Unit: 1791

of ordinary skill in the art to perform routine experimentation results in the claimed range of increase in hardness.

Hijkema discloses the coatings maybe designed to facilitate the acceptance of the stent into its applied surroundings or to enable the delivery of therapeutic to the lumen and its surroundings (paragraph 5), but does not specify the therapeutic is an antiproliferative drug. However, it is well known in medical devices such as stents for delivering a biologically active material to a desired location within the body of a patient wherein the biologically active material includes agents such as antiproliferative as shown by Rosenthal (paragraphs 1 and 121-126). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the well known biologically active agent for the stent of Hijkema.

Regarding claims 77-80, Hijkema teaches dependant upon the ambient temperature, the coating's preexisting temperature and the glass transition temperature of the coating, the temperature of the existing surface of the coating may be either heated or cooled (paragraph 30), but does not expressly disclose the specific temperature. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (see *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)). Therefore, it would have been obvious to one of ordinary skill in the art to perform routine experimentation results in the claimed range of temperature.

Response to Arguments

Applicant's arguments filed 5/18/2009 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant essentially argues that Hijkema fails to teach "temperature below room temperature" because in a preferred embodiment Hijkema teaches the temperature approximately 20 deg. C above the glass transition temperature. Upon further consideration, the Examiner found that even in the preferred embodiment of Hijkema, a temperature of 20 deg. C above the glass transition temperature of a polymer can still be below room temperature. Furthermore, in the general broader teaching of Hijkema, dependant upon the ambient temperature, the coating's preexisting temperature and the glass transition temperature of the coating, the temperature of the existing surface of the coating may be either heated or cooled. Therefore, Hijkema suggests cooling the coating to a desired temperature.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHU H. NGUYEN whose telephone number is (571)272-5931. The examiner can normally be reached on M-F.

Art Unit: 1791

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Phillip Tucker can be reached on 571-272-1095. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P.N 8/18/2009

/Philip C Tucker/
Supervisory Patent Examiner, Art Unit 1791